REMARKS

This is intended to be a full and complete response to the Office Action dated October 21, 2003, having a shortened statutory period for response set to expire on January 21, 2004. Claims 1-39 are pending in the application. Claims 22-39 have been withdrawn from consideration, though Applicant retains the right to present these claims in a divisional application. Claims 1-21 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting. Additionally, claims 1-21 stand rejected under 35 USC Section 112, first paragraph. Applicant respectfully traverses these rejections.

Double Patenting

Claims 1-21 stand rejected under the judicially-created doctrine of obviousness-type double patenting in light of USSN 09/705,603. Applicant avers that should USSN 09/705,603 issue prior to the issuance of the present application, and should the claims of the applications remain substantially unchanged, Applicant shall file a terminal disclaimer as appropriate.

35 U.S.C. Section 112, first paragraph: Enablement

Claims 1-21 remain rejected under 35 U.S.C., Section 112, first paragraph. The Examiner states that the specification does not reasonably provide enablement for using an immune complex to induce an immune response, where the complex is generated *in vitro* or *in vivo*. In the response of August 11, 2003, Applicant argued that the specification does provide a person of skill in the art with guidance in respect to using a vector encoding a bovine HSV antigen epitope expressed in cells, isolating the epitope-HSV complex from the vector-infected host cell line, and administering the epitope-HSV complex to an animal to elicit an immune response. However, the Examiner now argues that such a process is not demonstration of the method of *in vivo*, but is an alternative *in vitro* method.

Applicant respectfully disagrees. Claim 1 of the present invention is drawn to eliciting a humoral and cell-mediated immune response against a bovine virus

comprising combining at least one bovine viral epitope and at least one heat shock protein to form a purified epitope/heat shock protein complex, and administering an immune system-stimulating amount of this purified epitope/heat shock protein complex to an animal. Claim 14 further limits claim 1 by stating that the epitope/heat shock protein complex is formed *in vivo*.

Applicant believes that the Examiner is confusing *in vitro* or *in vivo* experimentation with where the epitope/heat shock protein complex is formed. The specification on pages 11 through 15 outlines several ways in which the epitope and heat shock protein can be obtained, as well as how complexes can be formed. For example, the epitope, the heat shock protein, or both may be synthesized by transfecting cells with a vector that expresses them. The expressed proteins are then purified, and then the epitope and heat shock protein are combined *in vitro* (that is, in a test tube) to obtain a complex. Alternatively, chemical synthesis can be used to obtain one or both of the epitope and heat shock components. Again, after purification, the epitope and heat shock protein can be combined *in vitro* (again, in a test tube) to form a complex. As yet another alternative, an expression vector expressing the epitope, for example, may be transfected into a cell that naturally expresses one or more heat shock proteins. In this way, the epitope and heat shock protein complex would be formed *in vivo*; that is, the complex is formed inside a cell, not in a test tube. Once the complex is formed *in vivo*, the complex can be purified in any number of ways and administered to an animal to stimulate the immune system. Thus, the issue is not whether the experiments are performed *in vivo* or *in vitro*; the issue is where the complexes are formed. Applicant considers a complex formed inside a living cell to be a complex formed *in vivo*.

In addition, the Examiner rejects claims 5-8 under 35 U.S.C. Section 112, first paragraph for enablement, stating that the specification does not teach which 5 to 25 amino acids should be used as the epitope for each pathogenic virus. Applicant respectfully disagrees.

First, it is known in the art that peptides presented by the MHC class I complex are 8- to 10-mers. In fact, in Gaddum, et al., *Veterinary Immunology and*

Immunopathology, 54: 211-19 (1996), cited against Applicant by the Examiner in the Examiner's Office Action of April 9, 2003, states, "it is well-established that CTLs (cytotoxic T lymphocytes) recognize processed foreign antigens as peptides, usually consisting of 8 to 10 amino acid residues, when associated with MHC class I molecules." Thus, Applicant asserts that one skilled in the art would, in light of what is known by the art regarding allele specific peptide motifs and the teaching of the present invention, understand that the 5 to 25 amino acid peptides, the 5 to 15 amino acid peptides, or the 8 to 10 amino acid peptides taught as useful in this specification should be those fragments of bovine viral proteins that comprise the MHC class I epitopes. Overall, the Applicant teaches that bovine viral epitopes, particularly peptides containing allele-specific peptide motifs, and more particularly, 8 to 10 amino acid fragments of allele-specific peptide motifs presented by the MHC class I complex, are useful as epitopes in the methods of the present invention. Applicant does not believe it is necessary need to teach specific peptide fragments for each allele-specific peptide motif for each bovine virus. Applicant believes that selecting the appropriate amino acids for the epitope of a particular bovine virus according to the methods of the present invention, would not require undue experimentation. Instead, selecting the appropriate epitope would simply require a review of the published literature for that particular bovine virus.

In view of the foregoing arguments, Applicant respectfully requests withdrawal of the rejections of claims 1-21 under 35 U.S.C. Section 112, first paragraph regarding enablement.

35 U.S.C. Section 112, first paragraph: Written Description

Claims 1-21 remain rejected under 35 U.S.C. Section 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully disagree.

The Examiner argues that the claimed invention is directed to the use of certain supermotifs or allele-specific peptide motifs, some with a particular-sized peptide.

However, the Examiner argues that the specification has not provided the structure for all HSP/epitope complexes. Applicant is somewhat confused by the rejection, but submits the following arguments.

According to section 2163.03 of the MPEP,

> "A description requirement issue can arise in a number of different circumstances where it must be determined whether the subject matter of a claim is supported in an application as filed.... While a question as to whether a specification provides an adequate written description may arise in the context of an original claim, which is not described sufficiently (see, e.g., Regents of the University of California v. Eli Lily, 119 F.3d 1559 (Fed. Cir. 1997)), there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. In re Wertheim, 541 F.2d. 257, 262 (CCPA 1976). Consequently, rejection of the original claim for lack of written description should be rare."

Moreover, section 2163.04 of the MPEP states, "the Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims (Wertheim, 541 F.2d. at 263.)."

Applicant wishes to point out that the specification teaches that heat shock proteins in combination with bovine viral epitopes are useful for immunizing animals. In particular, the specification teaches that bovine viral epitopes from viruses such as bovine viral diarrhea virus, bovine respiratory syncytial virus, parainfluenza virus III, bovine corona virus and bovine rota virus are useful. Even more particularly, the present specification teaches that proteins and peptides containing allele-specific peptide motifs may be used; 8 – 10 amino acid fragments may be used, and lists specifically bovine lymphocyte antigen-A11, bovine lymphocyte antigen-A20 and bovine lymphocyte antigens-HD1,-HD6 and –HD7. Applicant asserts that one skilled in the art would understand exactly what is encompassed by the written description and the instant claims. Applicant not only provides examples of useful viruses, but of specific allele-specific peptide motifs in the specification. The claims track the text and disclosure of the specification almost exactly. Thus, Applicant does not believe the

Examiner has presented by a preponderance of the evidence that a person skilled in the art would not recognize in the present disclosure a description of the invention defined by the claims. The Examiner states that the requirement for a written description and an enabling disclosure are separate. Applicant agrees. However, Applicant does not understand in what way the present claims are lacking in written description.

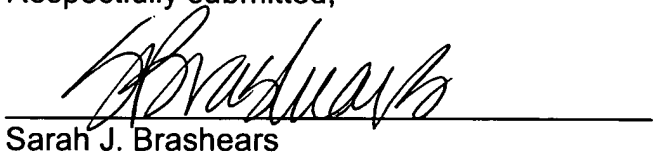
In view of the foregoing arguments, Applicant respectfully requests a withdrawal of the rejection of claims 1-21 under 35 U.S.C. Section 112, first paragraph for written description.

Conclusion

In conclusion, having addressed all issues set out in the Office Action, Applicant respectfully submits that claims 1-21 are in condition for allowance and respectfully requests that a timely Notice of Allowance be issued in this case.

If any matters can be handled by telephone, Applicant requests that the Examiner telephone Applicant's attorney at the number below. The Commissioner is authorized to charge any additional fees to Deposit Account No. 20-0782/UNEL/0002/SB.

Respectfully submitted,



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